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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,883	01/24/2002	Morten Lorentz Pedersen	PEDERSEN=1A	5403

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EXAMINER

HORLICK, KENNETH R

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/053,883

Applicant(s)

PEDERSEN, MORTEN LORENTZ

Examiner

Kenneth R Horlick

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2004 and 15 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-108 is/are pending in the application.
- 4a) Of the above claim(s) 86-93 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-85 and 94-108 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1. Claims 86-93 remain withdrawn from consideration.
2. Claims 1-85 and 94-108 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims are confusing because it cannot be determined what action(s) is required in the final step of independent claim 1, "obtaining at least one single stranded polynucleotide tag". Firstly, it is unclear what is encompassed by "obtaining"; that is, by what action one "obtains" said tag. Secondly, it is unclear what is encompassed by a "tag"; although this term is also used in the preamble, it cannot be determined from the claim as a whole what single stranded polynucleotide is to be "obtained", and is considered to be a "tag". Clarification is required.

3. With respect to the above rejection, the arguments of the response filed 08/30/04 have been fully considered, but are not found persuasive. The response states that "the tag is obtained because the nicked polynucleotide comprises it. 'Obtaining' is not really a separate step and hence step (iii) is converted to a 'thus' clause". However, this is not convincing because the recited "providing" and "contacting and cleaving" steps clearly do not result in "obtaining at least one single stranded polynucleotide tag". That is, in the absence of some type of separation, isolation, or denaturation step, no such single stranded polynucleotide is obtained.

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NEW GROUND OF REJECTION NECESSITATED BY THE AMENDMENT

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5, 6, 10-17, 39, and 106 are rejected under 35 U.S.C. 102(e) as being anticipated by Jack et al. (US 6,660,475).

These claims, as amended, are drawn to methods comprising the steps of providing a double stranded polynucleotide, and contacting and cleaving at least one of the strands with a cleavage agent capable of recognizing said polynucleotide and cleaving only one of the strands to provide a nicked double stranded polynucleotide which comprises a "tag". Significantly, in these amended claims no further steps are required, whereas in the prior claims a further step was apparently required, although the scope could not be determined.

As noted in the previous Office action in paragraph 6, Jack et al. disclose the two steps required in these amended claims (see especially Fig. 1A-1B). While Jack et al. do not specifically teach that a "tag" is formed by the nicking enzyme, any sequence may be considered as a potential tag since it may be detected by the complementary sequence. Thus, the method of Jack et al. satisfies the claim language. Regarding

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claim 39, Jack et al. also clearly teach a further step of separating the single stranded polynucleotide.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-9, 81, 83-85, and 105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jack et al.

These claims are drawn to the methods as rejected above, with further limitations regarding length and origin of the "tag", and use of a cleavage agent attached to a solid support such as a capillary tube or microfluidic device.

While these further limitations are not taught in the reference, one of ordinary skill in the art would have been motivated to apply them in the method of Jack et al. because they would have merely involved routine optimization, or conventional solid support technology, for known benefits. Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

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6. Claims 2-4, 18-38, 40-80, 82, 94-104, 107, and 108 are free of the prior art, but are rejected for other reasons. No claims are allowable. The further limitations in these claims are not taught or suggested in Jack et al., either alone or in combination with any other prior art.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kenneth R Horlick
Primary Examiner
Art Unit 1637

11/15/04